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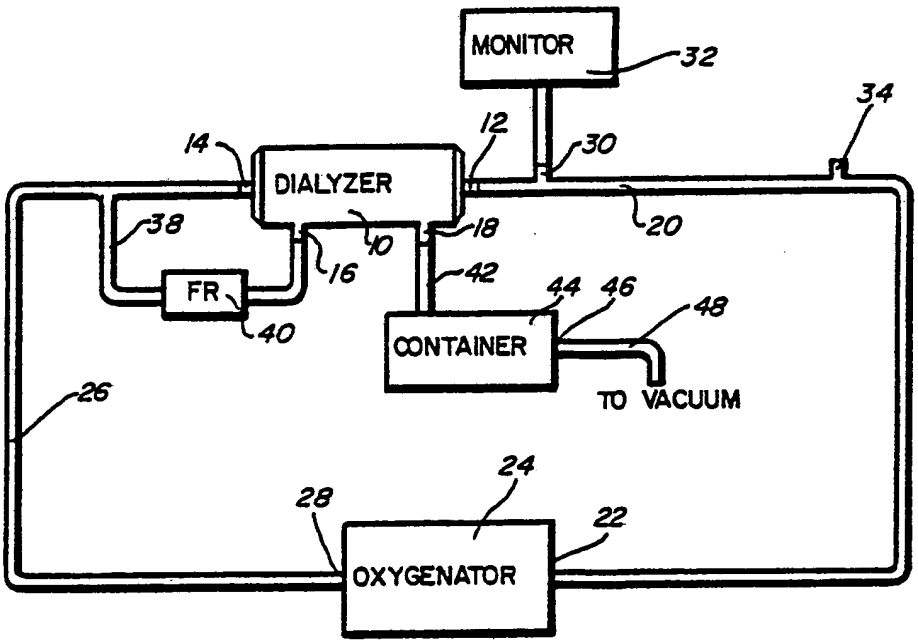

(57) Abstract

System for priming an ultrafiltration unit (10) connected to a blood source, without requiring a pump in the blood line. An ultrafiltration unit (10) is provided having an ultrafiltration membrane which separates a blood compartment from an ultrafiltrate compartment, a blood inlet port (12), a blood outlet port (14), a second inlet port (16) communicating with the ultrafiltrate compartment, and an ultrafiltrate outlet port (18). A feedback tube (38) connects the blood outlet port

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PRIMING SYSTEM FOR ULTRAFILTRATION UNIT

TECHNICAL FIELD

The present invention concerns a novel system for priming an ultrafiltration unit.

BACKGROUND ART

One of the problems in cardiac bypass surgery is that when the patient's blood has been fully diluted in a bypass circuit with priming solution, addition fluid and cardioplegia solution, the hematocrit has dropped to well under normal values. Since the patient cannot take back his own blood volume and the circuit volume, much of this diluted blood and the patient's blood cells and proteins are left in the oxygenator, heat exchanger and tubing. Recently, a high ultrafiltration hemodialyzer has been used to concentrate this blood by removal of water so that a reasonable volume of the valuable blood constituents can be given back to the patient. In this operational mode, a dialyzer is used only as an ultrafiltrator so that no dialysis solution flow is required. Ultrafiltration is achieved by drawing a vacuum on the dialysate compartment. Sometimes a blood pump is used, but often a tap is made in the circuit downstream of the bypass circuit arterial pump or venous pump in the oxygenator. Thus the circuit and ultrafiltration unit must be primed without a pump.

Dialyzers may require the rinsing of both the blood compartment and the dialysate compartment to prepare the dialyzer and to guard against the possibility of a hypersensitivity reaction in the patient. Of course the rinsing solution must be discarded.

The present invention is particularly applicable to any type of ultrafiltration unit, including a hemoconcentrator, a dialyzer, a diafilter, etc. Such ultrafiltration units generally include an ultrafiltration membrane which separates a blood compartment from an ultrafiltrate compartment. When a dialyzer is used as an ultrafiltration unit, the dialysate compartment of the dialyzer becomes the ultrafiltrate compartment.

It is an object of the present invention to provide a system for priming an ultrafiltration unit without requiring a pump in the blood line.

Another object of the present invention is to provide a system for priming an ultrafiltration unit with a provision for automatically discarding the priming solution without disconnection or reconnection of the blood set.

A further object of the present invention is to provide a system for priming an ultrafiltration unit, enabling the priming and rinsing of both the blood compartment and the ultrafiltrate compartment, at prescribed flow and volume rates and with an automatic discard of the priming and

rinsing solution without disconnection or reconnection of the blood set.

By avoiding the necessity of disconnecting or reconnecting the blood set before, during or after priming and/or rinsing, the sterility compromise concomitant with disconnection or reconnection is obviated.

Other objects and advantages of the present invention will become apparent as the description proceeds.

DISCLOSURE OF THE INVENTION

In accordance with the present invention, a system is provided for priming an ultrafiltration unit, connected to a blood source, without requiring a pump in the blood line. The system includes an ultrafiltration unit having an ultrafiltration membrane which separates a blood compartment from an ultrafiltrate compartment, a blood inlet port, a blood outlet port, a second inlet port communicating with the ultrafiltrate compartment, and an ultrafiltrate outlet port. A feedback tube connects the blood outlet port to the second inlet port, whereby a low pressure can be applied to the ultrafiltrate outlet port and priming solution introduced at the blood inlet port will be drawn through the ultrafiltration unit blood compartment as well as across the membrane and then through the ultrafiltrate compartment and out the ultrafiltrate outlet port.

In the illustrative embodiment, blood inlet tubing is provided for connecting the blood inlet port to a blood source. A first port is provided on the blood inlet tubing for connecting a pressure monitor to the blood inlet tubing. A second port is provided on the blood inlet tubing for connecting a priming solution container to the blood inlet tubing. Blood outlet tubing extends from the blood outlet port. Means are provided for connecting the ultrafiltrate outlet port to a container and means connect the container to a vacuum source.

In the illustrative embodiment, a flow restrictor is interposed in the feedback tube to control the flow rate of the priming solution through the blood path and then into the ultrafiltrate compartment.

In accordance with the present invention, a method is provided for priming an ultrafiltration unit connected to a blood source without requiring a pump in the blood line.

The method comprises the steps of providing an ultrafiltration unit having an ultrafiltration membrane which separates a blood

compartment from an ultrafiltrate compartment, a blood inlet port, a blood outlet port, a second inlet port communicating with the ultrafiltrate compartment and an ultrafiltrate outlet port; providing a feedback tube connecting the blood outlet port to the second inlet port; introducing priming solution to the blood inlet port; and applying a low pressure to the ultrafiltrate outlet port to draw the priming solution through the blood compartment as well as across the membrane, through the ultrafiltrate compartment, and out the ultrafiltrate outlet port.

In the illustrative embodiment, the method includes the steps of providing tubing for connecting the blood inlet port to a blood source; connecting a priming solution container to the blood inlet tubing; and prior to introducing the priming solution to the blood inlet port, (1) clamping the tubing upstream of the blood inlet port and introducing priming solution into the tubing upstream of the clamp; and (2) then clamping the tubing downstream of the feedback tube and removing the clamp upstream of the blood inlet port.

A more detailed explanation of the invention is provided in the following description and claims, and is illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic diagram of a system for priming an ultrafiltration unit, constructed in accordance with the principles of the present invention.

Figure 2 is a schematic diagram of the system of Figure 1, after a first step of priming has been accomplished.

Figure 3 is a schematic diagram of the system of Figure 1, after a second step of priming has been accomplished.

Figure 4 is a schematic diagram of the system of Figure 1, after the system has been fully primed.

DETAILED DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENT

Referring to the Figures, an ultrafiltration unit 10, in the exemplary form of a dialyzer, is illustrated having a blood inlet port 12, a blood outlet port 14, a second inlet port 16 and an ultrafiltrate outlet port 18. In a dialyzer, ports 16 and 18 would be the dialysate inlet port and the

dialysate outlet port, respectively. Ultrafiltration unit 10 includes a suitable ultrafiltration membrane separating the blood compartment from the ultrafiltrate compartment, as is well-known in the art.

A blood inlet tube 20 connects blood inlet port 12 to the outlet 22 of an oxygenator 24. A blood outlet tube 26 connects the blood outlet port 14 to the inlet 28 of oxygenator 24. This connection could be directly to the oxygenator illustrated or through a cardiotomy reservoir. Additionally, blood might be introduced into a blood bag or other container directly from the hemoconcentrator. The illustrated method is for explanation only and not to restrict the choice of blood inlet source or outlet final destination.

Blood inlet tube 20 includes a first port 30 for enabling the connection of a pressure monitor 32 to the blood inlet tube 20. The blood inlet tube 20 also has a second port 34 for enabling the connection of a priming solution container 36 (Figures 2-4) or rinsing solution container to the blood inlet tube 20.

A feedback tube 38 having a flow restrictor 40 is connected from blood outlet port 14 to the second inlet port 16. The second inlet port 16 communicates with the ultrafiltrate compartment of unit 10. The flow restrictor 40 operates to control the flow rate through the ultrafiltration unit 10 as will be explained below.

A priming solution output tube 42 connects ultrafiltrate outlet port 18 to a container 44 with the outlet 46 of container 44 being coupled to a vacuum source via tubing 48. Often the hospital has a wall vacuum which is connected to tubing 48.

The operation of the system will now be explained. Referring to Figure 2, blood inlet tubing 20 is clamped at point 50 and a container 36 of priming solution such as saline solution, is attached to port 34. The portion of tubing 20 between point 50 and the oxygenator is then primed. Referring to Figure 3, the clamp is removed at point 50, the blood inlet tubing is clamped at point 52 (upstream of port 34) and the blood outlet tubing 26 is clamped at point 54 (downstream of the feedback tube 38). A vacuum of determined level such as 500 mm mercury is applied at ultrafiltrate outlet port 18.The priming fluid will be drawn from container 36 through the blood compartment of ultrafiltration unit 10, to point 54, through flow restrictor 40, into the ultrafiltrate compartment via second inlet port 16, out of ultrafiltrate outlet port 18 and to drain via tube

48. It can be seen that flow restrictor 40 controls the flow rate of the fluid into the ultrafiltrate compartment.

As the priming fluid flows through the blood compartment of ultrafiltration unit 10, some of it will be ultrafiltered through the membrane. The ultrafiltration unit will be rinsed, flushed and primed with the solution automatically discarded to drain. After about five minutes, in the illustrative embodiment, approximately 800 to 900 ml of priming solution will have passed through the ultrafiltration unit 10.

Referring to Figure 4, after the ultrafiltration unit 10 has been primed, the clamps at points 52 and 54 are removed and clamps are provided at points 56 and 58, to stop the feedback line and to remove the vacuum. In this manner, the remaining portion of the blood outlet tubing 26 is primed using the remaining solution in container 36 and the line is clamped at points 60 and 62. The system is now ready for use. Clamp 56 remains in place but clamps 58, 60 and 62 are removed and the correct negative pressure is applied at ultrafiltrate outlet port 18 to control ultrafiltration.

It can be seen that a novel system has been disclosed for priming and rinsing an ultrafiltration unit, such as a dialyzer, hemoconcentrator or diafilter, without requiring the use of a pump in the blood line. Both the blood compartment and ultrafiltrate compartment are rinsed at a controlled rate and the solution is automatically discarded without disconnection or reconnection of the blood tubing which could result in sterility compromise.

Although an illustrative embodiment of the invention has been shown as described, it is to be understood that various modifications and substitutions may be made by those skilled in the art without departing from the novel spirit and scope of the present invention.

WHAT IS CLAIMED IS:

1. In a system for priming an ultrafiltration unit, connected to a blood source, without requiring a pump in the blood line, an ultrafiltration unit having an ultrafiltration membrane which separates a blood compartment from an ultrafiltrate compartment, a blood inlet port, a blood outlet port, and an ultrafiltrate outlet port; the improvement comprising:

a second inlet port communicating with the ultrafiltrate compartment;

a feedback tube connecting the blood outlet port to the second inlet port whereby a low pressure can be applied to the ultrafiltrate outlet port and priming solution introduced at the blood inlet port will be drawn through the blood compartment and then through the ultrafiltrate compartment and out the ultrafiltrate outlet port.

2. In a system as described in Claim 1, including blood inlet tubing for connecting the blood inlet port to a blood source, a first port on the blood inlet tubing for connecting a pressure monitor to the blood inlet tubing, a second port on the blood inlet tubing for connecting a priming solution container to the blood inlet tubing, and blood outlet tubing extending from the blood outlet port.

3. In a system as described in Claim 1, including means for connecting the ultrafiltrate outlet port to a container and means for connecting the container to a vacuum source.

4. In a system as described in Claim 1, including a flow restrictor interposed in the feedback tube to control the flow rate into the ultrafiltrate compartment.

5. In a system for priming an ultrafiltration unit, connected to a blood source, without requiring a pump in the blood line, an ultrafiltration unit having an ultrafiltration membrane which separates a blood compartment from an ultrafiltrate compartment, a blood inlet port, a blood outlet port, and an ultrafiltrate outlet port, the improvement comprising:

a second inlet port communicating with the ultrafiltrate

compartment;

a feedback tube connecting the blood outlet port to the second inlet port whereby a low pressure can be applied to the ultrafiltrate outlet port and priming solution introduced at the blood inlet port will be drawn through the blood compartment and then through the ultrafiltrate compartment and out the ultrafiltrate outlet port;

a flow restrictor interposed in the feedback tube to control the flow rate into the ultrafiltrate compartment;

blood inlet tubing for connecting the blood inlet port to a blood source;

a first port on the blood inlet tubing for connecting a pressure monitor to the blood inlet tubing;

a second port on the blood inlet tubing for connecting a priming solution container to the blood inlet tubing;

blood outlet tubing extending from the blood outlet port; and

means for connecting the ultrafiltrate outlet port to a vacuum source.

6. In a system as described in Claim 5, in which said ultrafiltration unit is a hemoconcentrator.

7. In a system as described in Claim 5, in which said ultrafiltration unit is a dialyzer, said second inlet port is a dialysis solution inlet port and said ultrafiltrate outlet port is a dialysis solution outlet port.

8. An ultrafiltration set which can be primed without requiring a pump on the blood line, comprising:

an ultrafiltration unit having an ultrafiltration membrane which separates a blood compartment from an ultrafiltrate compartment;

a blood inlet port;

a blood outlet port;

a second inlet port communicating with the ultrafiltrate compartment;

an ultrafiltrate outlet port;

blood inlet tubing for connecting the blood inlet port to a blood source;

a first port on the blood inlet tubing for connecting a pressure monitor to the blood inlet tubing;

a second port on the blood inlet tubing for connecting a priming solution container to the blood inlet tubing;

blood outlet tubing extending from the blood outlet port;

a feedback tube connecting the blood outlet port to the second inlet port, whereby a low pressure can be applied to the ultrafiltrate outlet port and priming solution introduced at the blood inlet port will be drawn through said blood compartment and then through said ultrafiltrate compartment and out the ultrafiltrate outlet port.

9. An ultrafiltration set as described in Claim 8, including a flow restrictor interposed in the feedback tube to control the flow rate into the ultrafiltrate compartment.

10. A method for priming an ultrafiltration unit connected to a blood source without requiring a pump in the blood line, comprising the steps of:

providing an ultrafiltration unit having an ultrafiltration membrane which separates a blood compartment from an ultrafiltrate compartment, a blood inlet port, a blood outlet port, a second inlet port communicating with the ultrafiltrate compartment, and an ultrafiltrate outlet port;

providing a feedback tube connecting the blood outlet port to the second inlet port;

introducing priming solution to the blood inlet port; and

applying a low pressure to the ultrafiltrate outlet port to draw the priming solution through the blood compartment, through the ultrafiltrate compartment and out the ultrafiltrate outlet port.

11. A method as described in Claim 10, including the steps of:

providing tubing for connecting the blood inlet port to a blood source;

connecting a priming solution container to the blood inlet tubing;

prior to introducing priming solution to the blood inlet port, (1) clamping the tubing upstream of the blood inlet port and introducing

priming solution into the tubing upstream of the clamp, (2) then clamping the tubing downstream of the feedback tube and removing the clamp upstream of the blood inlet port, whereby the priming solution will be drawn through the blood compartment, through the ultrafiltrate compartment, and out the ultrafiltrate outlet port.

FIG. 1

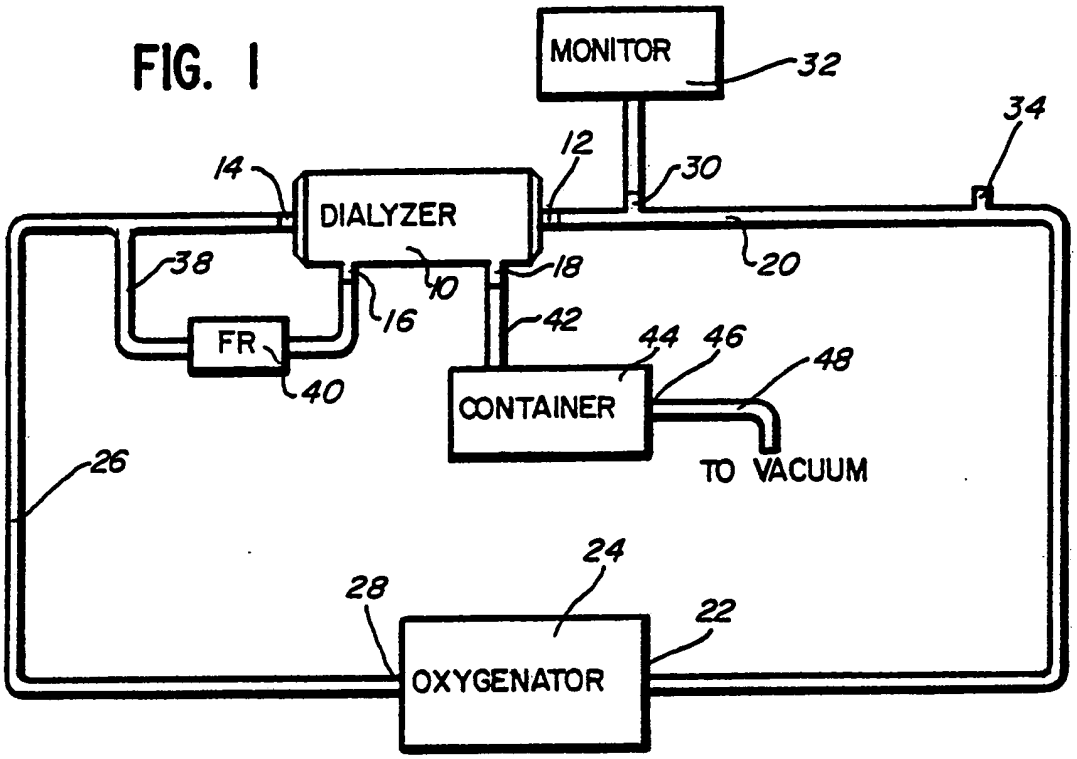
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FIG. 2

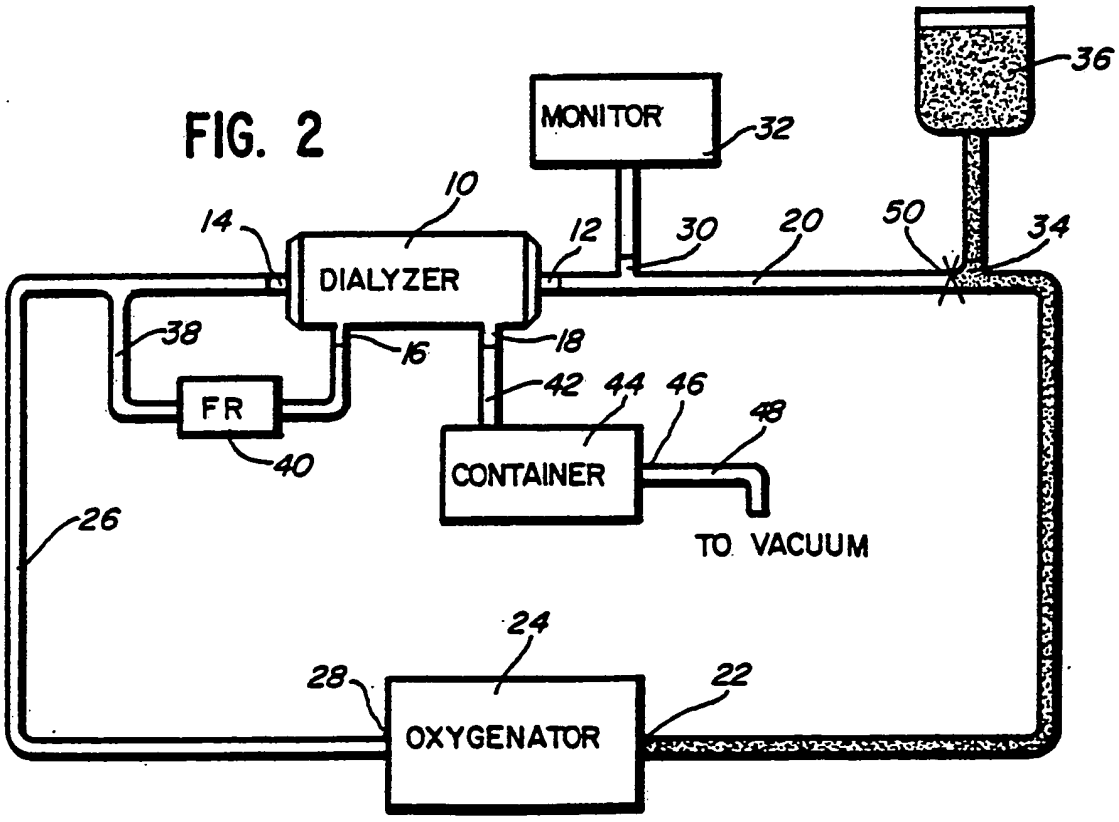
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FIG. 3

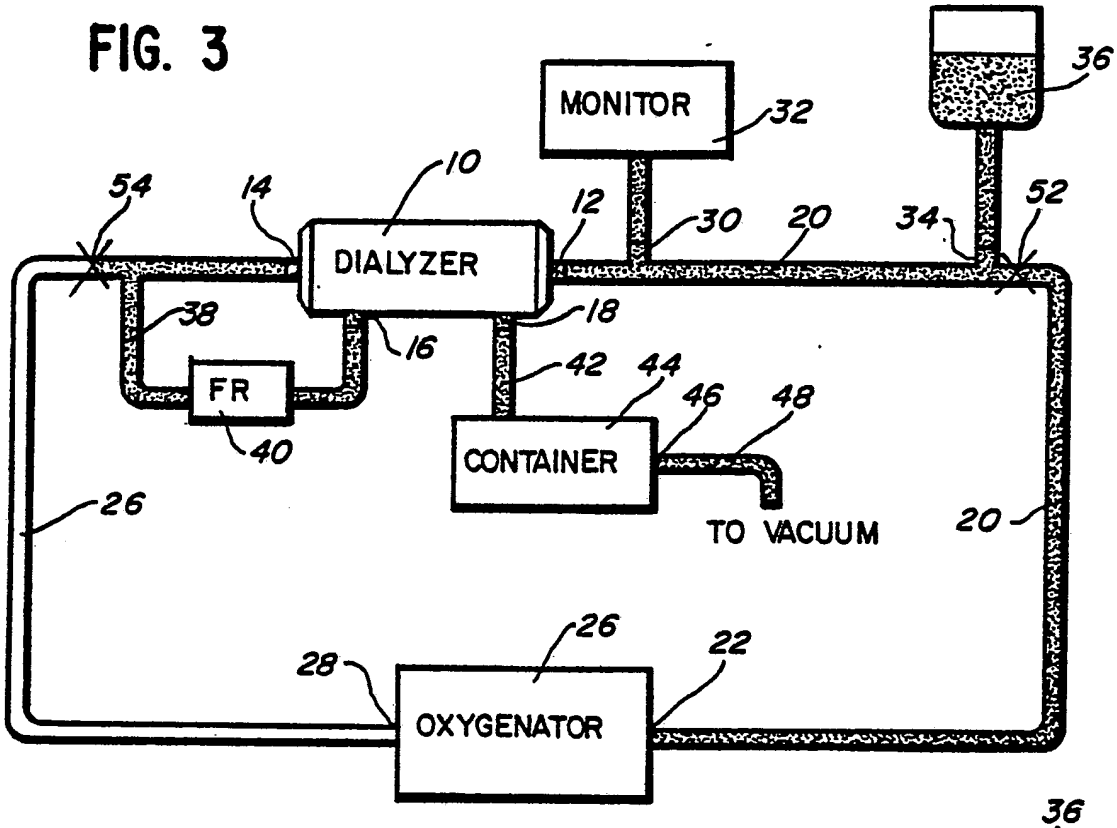
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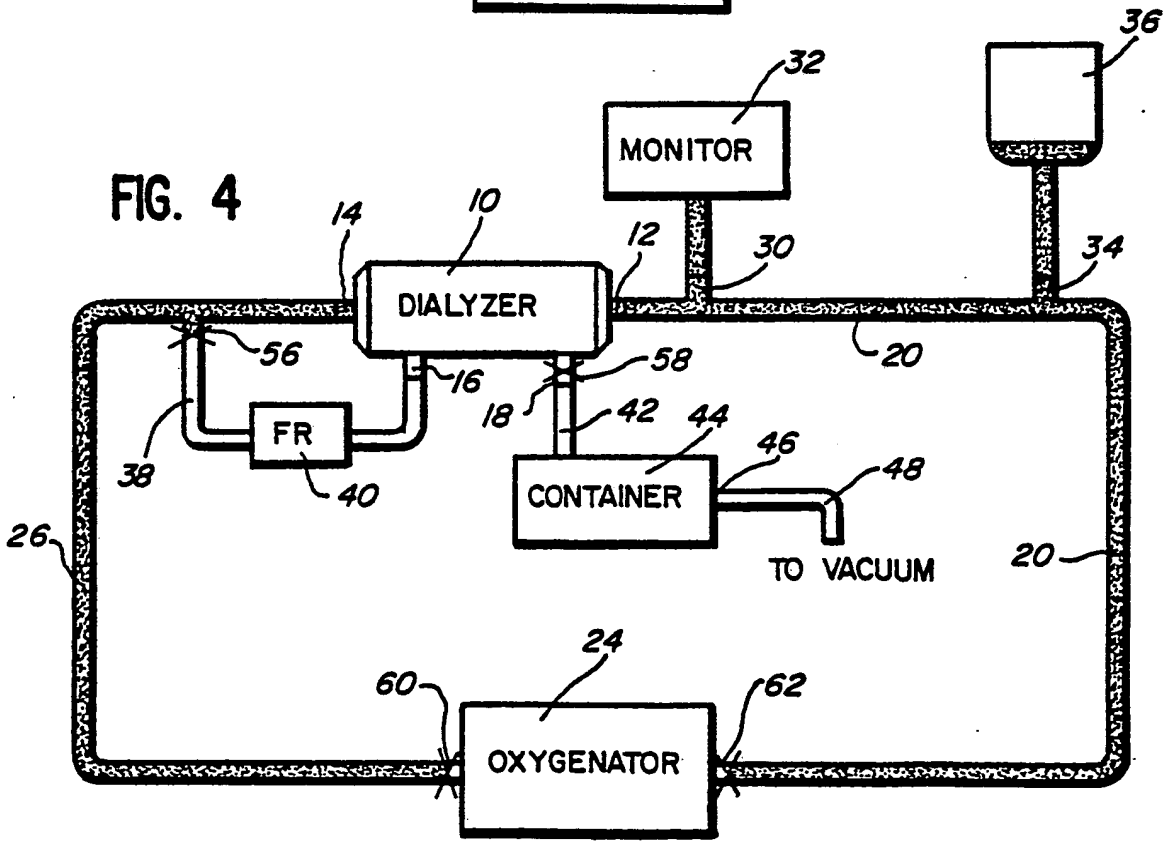
FIG. 4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OXYGENATOR

INTERNATIONAL SEARCH REPORT

International Application No PCT/US85/00124

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

INT. CL.[4] A61M 1/03
U.S. CL. 210/651

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	210/647, 321.4, 433.2 422/47, 48 128/DIG. 3

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X	US,A, 4,299,705, PUBLISHED 10 NOVEMBER 1981, RUSSELL	1-11
A	US,A, 3,907,504, PUBLISHED 23 SEPTEMBER 1975; Hammond et al.	
A	US,A, 3,927,980, PUBLISHED 23 DECEMBER 1975, LEONARD	

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IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
28 FEBRUARY 1985	13 MAR 1985
International Searching Authority [1]	**Signature of Authorized Officer [20]**
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